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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,556	11/06/2003	Chandralata Raghukumar	Q78361	8327
23373	7590	05/24/2007		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/701,556

Applicant(s)

RAGHUKUMAR ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed 5/15/07 is acknowledged.

Claims 16-21 are being considered on the merits. Claims 1-15 and 22 are withdrawn from consideration as directed to a non-elected invention.

It is noted that a substitute specification is required pursuant to 37 CFR 1.125(a) will be filed in due course.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is stated in the last Office action.

Applicant's averments are noted. However, a statement is missing averring **that all restrictions on the availability to the public of the material deposited will be irrevocably removed upon the granting of a patent.**

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Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for “Fe₂SO₄⁻¹ seawater” as now recited in claim 16 (c).

No basis or support is found in the present specification for the recitation “spray-dried dairy in a concentration of 1% (w/v) as now recited in claim 21.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague, indefinite and confusing in that there is no clear consistency between the preamble directed to culturing a specific strain and the body of the claim directed to “growing an *Aspergillus* sp. fungal strain under certain process conditions and recovering a supernatant therefrom.

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Claim 16 is confusing in the recitation “”wherein said medium exhibits a with a pH range of 7.0 to 9.0”. It is unclear what is intended. In any event, the term “exhibits” renders the claim indefinite. It is suggested that the phrase be replaced by “has a pH range of...”. See, also, claim 18.

Claim 16 is vague, indefinite and confusing in that the intended meaning of “ $\text{Fe}_2\text{SO}_4^{-1}$ seawater” cannot be readily assessed. “Seawater” appears to be a separate substance from the sulfate. In addition, the particular sulfate disclosed does not appear to exist.

In claim 16, the replacement of “the” by “a” appears incorrect, since one and only one cell free clear supernatant solution is obtained in step (d).

Claims 18 and 19 fail to find antecedent basis in claim 16 for growing strain *Aspergillus* sp. 5102.

Claim 21 is vague and indefinite in the recitation of “spray-dried dairy in a concentration of 1% (w/v)”. It is unclear what is intended by this recitation, even when reading the claim in light of the specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nehra *et al.* taken with Sindhu *et al.*, Malathi *et al.* and Atlas *et al.*

The claims are directed to a process of producing a low temperature alkaline protease with a specific *Aspergillus* strain using certain conditions.

Nehra *et al.* disclose the production of an alkaline protease with an *Aspergillus* strain, wherein the fungal mat was used to obtain a starter culture and submerged fermentation, which is

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presumed to be “shallow” and which appear to be static. See, e.g., page 44, Results and Discussion. In addition, Nehra *et al.* disclose various nitrogen sources, including soybean meal and casein, for example.

The process differs from the claimed invention in the use of certain culture medium additives. However, Malathi *et al.* adequately demonstrate that the use of malt extract, corn steep liquor, and soybean meal are all old and well known additives used for the cultivation of *Aspergillus* for the production of alkaline proteases. See, e.g., page 714, Table I. The alkaline protease produced appears to constitute a “low temperature” alkaline protease in that loss of activity occurs at 32° C as compared with 28° C.

The process further differs from the claimed invention in that the properties of the strain cultured in Nehra *et al.* and Malathi *et al.* are not clearly delineated. However, inasmuch as the strains belong to the same genus *Aspergillus*, it is apparent that they are substantially similar.

In addition, Sindhu *et al.* disclose the production of alkaline protease by various fungi, several of which are *Aspergillus* strain. See, e.g., page 27, Table II.

The use of “Czapek Dox broth” in the cultivation of *Aspergillus* is old and well known in the art. See, e.g., Atlas *et al.*, pages 279-280. Moreover, the use of glucose in the medium is disclosed by Nehra *et al.*, page 44, Table 1 and *Aspergillus* are recognized in the art as cellulase producers.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Nehra *et al.* and Malathi *et al.* by culturing further *Aspergillus* strains as suggested by the teachings of Sindhu *et al.* and adjusting process conditions to optimize the protease production for the expected benefit of maximizing production of useful low temperature alkaline proteases for various industrial and pharmaceutical applications, including as a depilation agent.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments that the references teach *A. flavus* is noted. However, at least Nehra *et al.* do not identify their preferred strain as to species. Therefore the basis for this argument is unclear. Moreover, there is no clear indication on this record as to the species of the strain disclosed in the instant written disclosure. In addition, and more importantly, and as also noted *supra*, in the rejection under 35 U.S.C § 112, second paragraph, from the claims as written, the identity of the *Aspergillus* strain cultured is at least ambiguous, since the material cultured is not identified by a strain designator.

As to Table 4, its relevance to the obviousness rejection of record is not clearly apparent, since there does not seem to be a comparison with the prior art as applied in the rejection.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

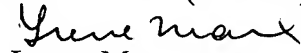
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
Art Unit 1651